IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

EARL RINGO, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**No. 09-4095-CV-C-NKC**
	)	
GEORGE A. LOMBARDI, et al.,	)	
	)	
Defendants.	)	

Suggestions in Opposition to Defendants' Renewed Motion to Dismiss

Defendants are state actors who plan to execute Plaintiffs Earl Ringo, John Middleton, Russell Bucklew, and John Winfield by injecting them with sodium thiopental (theoretically causing unconsciousness), pancuronium bromide (a paralytic agent), and potassium chloride (which induces a massive heart attack). The latter two drugs will cause excruciating pain if the prisoner is not adequately anesthetized.[1]

Plaintiffs seek a declaratory judgment that Defendants' plans violate the Food, Drug and Cosmetic Act (FDCA)[2] and the Controlled Substances Act (CSA).[3] Thiopental is a Schedule III controlled substance, and the CSA forbids the dispensing of any such substance without a prescription from a medical practitioner who is federally licensed and registered to issue it.[4] The FDCA similarly requires that such a "drug" be dispensed with a prescription issued by a "a practitioner licensed by law to administer such drug."[5] The Act more generally requires that

---

[1] *Baze v. Rees*, 128 S. Ct. 1520, 1533 (2008) (calling this proposition "uncontested").

[2] 21 U.S.C. §§ 301 *et seq.*

[3] 21 U.S.C. §§ 801 *et seq.*

[4] 21 U.S.C. §§ 822(a), 829(b), 842(a)(1).

[5] 21 U.S.C. § 353(b)(1).

drugs be approved by the FDA before they are administered, and that they be proven effective for their intended purposes.[6] Defendants appear to concede that they will not seek or obtain any prescriptions, that the drugs will not be administered by licensed practitioners, and that no federal agency has approved the chosen drugs for the planned purposes—including the use of thiopental to prevent severe pain from the other two drugs.

Defendants now move to dismiss, arguing that Plaintiffs lack a sufficient remedy for Article III standing, that the suit is barred by the res judicata effect of a previous lethal injection case, that the FDCA and CSA do not permit a civil enforcement suit by a non-governmental party, and that the statutes do not preempt state law concerning lethal injection. All of these arguments fail. First, Plaintiffs demonstrate adequate "redressability" for standing precisely because public officials are presumed to follow the law, as Defendants likely would if the Court were to definitively declare that their conduct violates the FDCA and CSA, and subjects them to civil and criminal sanctions.[7] Second, Defendants' res judicata defense rests on matters beyond Plaintiffs' complaint and is premature on a motion to dismiss, but, in any event, the previous litigation did not involve the same plaintiffs or their privies, did not necessarily involve the same defendants, and did not arise from the same nucleus of operative fact. Third, Plaintiffs are not "enforcing" the FDCA or CSA by seeking damages or an injunction, but rather, seek a declaratory judgment under these statutes as courts routinely allow private parties to do. Finally, the FDCA and CSA need not exhaustively preempt Missouri lethal injection law or Missouri controlled substances law in order for Defendants' individual actions to violate the FDCA and CSA—which they do under the plain language as well as the purposes of both statutes.

---

[6]21 U.S.C. § 355(a),(b).

[7]*See*, *e.g.*, *Franklin v. Massachusetts*, 505 U.S. 788, 803 (1992).

I. Plaintiffs have standing because, for Article III purposes, there is a sufficient likelihood that Defendants would abide by a declaratory judgment stating that their actions are illegal and subject them to prosecution.

Defendants exaggerate the "redressability" requirement of Article III standing, which is "a matter of probabilities rather than certainties."[8] A plaintiff need not show that the requested relief will automatically cure the claimed injury. In *Friends of the Earth. v. Laidlaw Environmental Services*, for example, individual citizens alleged that mercury discharges from a wastewater treatment plant kept them from fishing and boating in certain portions of a river.[9] They brought suit under the Clean Water Act, seeking the remedy of civil penalties payable to the federal treasury. The Court held that the injuries were sufficiently redressable through monetary penalties even though the plaintiffs had stopped seeking injunctive relief. It sufficed that the reliefs the plaintiffs sought were likely to deter future violations, and the tainted waterways might become usable again.[10]

Plaintiffs here seek a declaration that Defendants' proposed actions violate the CSA and the FDCA. Defendants now believe that their actions accord with these statutes.[11] But if faced with a definitive and final declaration to the contrary, Defendants would learn that their actions would subject them to possible prosecution. That possibility may well change the behavior of Defendants, who are free to adopt and implement a method of "lethal injection" or "lethal gas"

---

[8] *Bruggeman ex rel. Bruggeman v. Blagojevich*, 324 F.3d 906, 910 (7th Cir. 2003) (Posner, J.).

[9] 528 U.S. 167, 181-83 (2000).

[10] *Id.* at 185-88; *accord Bruggeman*, 324 F.3d at 910 (potential benefit to plaintiffs from the relief sought was "speculative [b]ut not so speculative as to as to negate standing").

[11] Amended Motion to Dismiss (ECF Doc. 29), at 14-20.

that doesn't use controlled substances or otherwise violate federal law.[12] In the State of Washington, for example, the DOC's medical director—who was not a member of the execution team—resigned when lethal injection drugs were requisitioned from the DOC pharmacy without a prescription, and after the prison superintendent refused to return those drugs to the pharmacy.[13] Thus, it would be reasonable to conclude that if this Court declares that how the DOC obtains and administers the lethal injection drugs violates the FDCA and the CSA, Defendants would be just as concerned as the medical director in Washington was, and would take action to bring their lethal injection procedures into conformance with the law.

One need not speculate that Defendants would abide by an authoritative declaration of the law. Courts presume that public officials will perform their duties lawfully.[14] That presumption creates ample "redressability" under the circumstances. In *Franklin v. Massachusetts*,[15] for example, the Commonwealth of Massachusetts and two of its voters challenged the reapportionment of House seats based on the 1990 census, alleging that Massachusetts lost a House seat because, among other things, the Secretary of Commerce violated the "actual Enumeration"[16] requirement by including overseas military personnel within each state's population count. One problem with the plaintiffs' claims was that the President himself is

---

[12] Mo. Rev. Stat. § 546.720.1.

[13] *See* Jonathan Martin, "State's Top Prisons Doctor Quit Over Execution Policy," *The Seattle Times*, June 23, 2009.

[14] *See*, *e.g.*, *Fidelity & Cas. Co. of New York v. Brightman*, 53 F.2d 161, 166 (8th Cir. 1931); *Potter v. Ciccone*, 316 F. Supp. 703, 706 n.2 (W.D. Mo. 1970); *Dittmeier v. Missouri Real Estate Commission*, 316 S.W.2d 1, 5 (Mo. 1958).

[15] 505 U.S. 788 (1992).

[16] *See* U.S. Constitution Art. I, § 2, cl. 3; Am. 14, § 2 ("Representatives shall be apportioned among the several States according to their respective numbers, counting the whole number of persons ***in each State***, excluding Indians not taxed.)

responsible for allocating House seats by issuing a report to Congress. The Supreme Court doubted that a court could enjoin the President from submitting the allegedly flawed report based on the allegedly illegal counting of military personnel. Plaintiffs nevertheless had standing to seek declaratory relief against the Secretary herself, who would presumably obey the law: "[W]e may assume it is substantially likely that the President and other executive and congressional officials would abide by an authoritative interpretation of the census statute and constitutional provision by the District Court, even though they would not be directly bound by such a determination."[17]

Plaintiffs cannot be certain that Defendants would comply with a declaration that their proposed conduct is illegal and subjects them to possible prosecution. They need not be. Quite aside from the prospect of contempt remedies,[18] Defendants are "substantially likely" to comply with the law declared by this Court, or by another tribunal on appeal. To assume otherwise would brand Defendants as lawless—a presumption prohibited by *Franklin*.

II. Res judicata does not bar the present suit.

Defendants argue that the present suit is precluded by an asserted res judicata effect of the district court's dismissal in *Clemons v. Crawford*, which is now on appeal.[19] Because Defendants' motion relies on matters outside the complaint, it should be construed as a motion for summary judgment and treated as such—i.e., allowing discovery before ruling on it. But,

---

[17] *Franklin*, 505 U.S. at 803. The plurality went on to reject the merits of the plaintiffs' constitutional claims, as did a concurrence of four additional justices. *Id.* at 806 (plurality); *id.* at 820 (Stevens, J., concurring). Only Justice Scalia found a lack of redressability. *Id.* at 824-25 (Scalia, J., concurring in part).

[18] *See* Amended Motion (ECF Doc. 29), at 3-4.

[19] *See Clemons et al. v. Crawford et al.*, Case no. 07-4129-CV-C-FJG (judgment entered July 15, 2008); *Clemons et al. v. Crawford et al.*, Case nos. 08-2895, 08-2807, 08-2813, 08-2894 (Eighth Circuit oral argument held Feb. 11, 2009).

even if considered now, it must fail. Res judicata depends upon "(1) whether the prior judgment was rendered by a court of competent jurisdiction; (2) whether the judgment was a final judgment on the merits, and (3) whether the same cause of action and same parties or their privies were involved in both cases."[20] Res judicata is an affirmative defense, and as such, the party invoking it bears the burden of proving that it applies.[21] Defendants fail to carry their burden because the two cases do not involve the same parties or the same causes of action.

A. Defendants' motion relies on matters outside the pleadings, making it a *de facto* motion for summary judgment that should not be decided until Plaintiffs are afforded full and fair discovery.

Despite seeking dismissal under Rule 12(b)(6), Defendants rely on earlier motions to intervene in *Clemons* filed by Plaintiffs Ringo, Bucklew, and Middleton, to argue that these Plaintiffs were in privity with the *Clemons* plaintiffs.[22] But these and all *Clemons* documents are outside the pleadings, and therefore, Defendants have essentially moved for summary judgment rather than dismissal. Rule 12(d) provides that "when matters outside the pleadings are presented and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56." A court should not dismiss on the basis of preclusion when the preclusion is not apparent from within the four corners of a plaintiff's complaint.[23] For this reason, "generally a res judicata contention cannot be brought in a motion to dismiss; it must be pleaded as an affirmative defense."[24] This Court recognized as much in

---

[20] *Gurley v . Hunt*, 287 F.3d 728, 731 (8th Cir. 2002).

[21] *Taylor v. Sturgell*, 128 S. Ct. 2161, 2179-80 (2008).

[22] Amended Motion to Dismiss (ECF Doc. 29), at 7-8.

[23] *See*, *e.g.*, *Rycoline Products v. C & W Unlimited*, 109 F.3d 883, 886-87 (3rd Cir. 1997).

[24] *Test Masters Educational Servs. v. Singh*, 428 F.3d 559, 570 n.2 (5th Cir. 2005) (citing 5 Wright & Miller, *Federal Practice & Procedure* § 1357 (3d ed. 2002)).

DePugh v. Clemens.[25] There, a plaintiff sued a police chief for executing an allegedly illegal warrant to search the plaintiff's home. The police chief moved to dismiss, asserting res judicata and collateral estoppel based on an earlier suit against himself and an additional officer. The Court converted the motion to a motion for summary judgment, and only on that basis considered matters beyond the plaintiff's complaint.[26]

Plaintiffs' insistence that this Court construe Defendants' motion as one for summary judgment is not merely academic. A proper conversion to summary judgment includes giving the non-moving party "an opportunity to take appropriate steps (including, if necessary, conducting discovery) to . . resist [the motion]."[27] One could not hold that res judicata applied without affording these Plaintiffs that opportunity. For example, we know that res judicata requires identical parties or their privies. Plaintiffs need not necessarily know the executioners' names,[28] but discovery will reveal what types of personnel are procuring and administering the drugs, any qualifications they might have to do so, and the source of the drugs. In other words, discovery will establish whether the individuals involved in Missouri lethal injections comply with the language of the CSA and FDCA, and even whether they did in the past but not in the present—something that would also be relevant to the applicability of the statutes because efforts to comply or avoid attempts to comply when attempts were previously made could constitute an admission that the CSA or FDCA apply to lethal injections.

---

[25]966 F. Supp. 898 (W.D. Mo. 1997) (Laughrey, J.).

[26]*Id.* at 900-01.

[27]*Gibb v. Scott*, 958 F.2d 814, 817 (8th Cir. 1992).

[28]*See* Mo. Rev. Stat. § 546.720.3.

B. Res judicata does not bar this suit because: 1) the present suit and *Clemons* involve different plaintiffs, who are not privies for purposes of res judicata, 2) the two suits involve or may involve different defendants, and 3) *Clemons* and this case involve different operative facts.

Without waiving their objection that Defendants' motion is premature, Plaintiffs will nevertheless explain below why res judicata does not bar this action.

1. Different plaintiffs

The most straightforward reason why *Clemons* does not bar this case is that the two cases feature different parties. Defendants make much of the fact that Plaintiffs Bucklew, Middleton and Ringo moved to intervene in *Clemons*. But they neglect to mention that the court denied them leave to do so[29]—a fact that forecloses preclusion.[30] These plaintiffs were, therefore, not parties to *Clemons*, and Plaintiffs Winfield and Skillicorn did not seek to join *Clemons*.

Neither were Plaintiffs Winfield, Bucklew, Ringo and Middleton "in privity" with the *Clemons* plaintiffs. Defendants argue that all current Plaintiffs are death-sentenced inmates, and thus, had the same legal interest in challenging the State's method of execution.[31] Defendants read the concept of "privity" too broadly. A unanimous Supreme Court in *Taylor v. Sturgell* recently rejected the notion of "privity" through "virtual representation."[32] Even when a non-party shares a party's legal position and interests, res judicata will not generally bar a suit by the non-party.[33] If the law were otherwise, then each and every lawsuit would be deemed a "class

---

[29]*Clemons et al. v. Crawford et al.*, No. 07-4129-CV-C-FJG, Order of July 15, 2008 (ECF Doc. 89).

[30]*Provident Life & Accident Ins. Co. v. Linthicum*, 930 F.2d 14, 16 (8th Cir. 1991); *Miami Showmen's Ass'n v. Everybody's Tabernacle*, 175 F.2d 1023, 1024 (5th Cir. 1949).

[31]Amended Motion to Dismiss (ECF Doc. 29), at 7-8.

[32]128 S. Ct. 2161 (2008).

[33]*Id.* at 2173-76.

action" encompassing all parties whose legal interests match the plaintiff's—but without any of the procedural protections governing class actions.[34] That is not the law. And, at any rate, a defendant may move for class certification.[35] The *Clemons* defendants never did so. Having done nothing in the district court to transform *Clemons* into the decisive and "global" action that they now claim it to be,[36] the *Clemons* defendants should not be heard to argue that the litigation was binding on non-parties.

The force of precedent will, of course, bind future parties to issues actually resolved in *Clemons* and its appeal. That is the purpose of *stare decisis*. But that doesn't mean ***any*** death-sentenced prisoner is barred from litigating claims that were absent from a suit that he did not or could not join.[37] Indeed, the State itself routinely argues that a lethal injection claim is "speculative" until an execution is scheduled, at which point the method of execution can be known.[38] This argument has prevailed.[39] For Defendants ***now*** to argue that *Clemons* was a "global" suit to definitively end all method-of-execution cases is nothing short of astounding.[40]

---

[34]*Id.* at 2176.

[35]*See*, *e.g.*, *In re Northern Dist. of California Dalkon Shield IUD Products Liability Litigation*, 526 F. Supp. 887, 895-96 (N.D. Cal. 1981); *Argo v. Hills*, 425 F. Supp. 151, 159 (E.D.N.Y. 1977).

[36]Amended Motion to Dismiss (ECF Doc. 29), at 7.

[37]*See Taylor*, 128 S. Ct. at 2171-72 (discussing general rule against non-party claim preclusion).

[38]*Strong v. State*, 2008 WL 3246348, at *93-*94 (State's brief); *State v. Barton*, 2007 WL 2113556, at *89-*90 (State's brief).

[39]*Strong v. State*, 263 S.W.3d 636, 654 (Mo. 2008); *State v. Barton*, 240 S.W.3d 693, 711 (Mo. 2007); *Worthington v. State*, 166 S.W.3d 566, 583 n.3 (Mo. 2005).

[40]Amended Motion to Dismiss (ECF Doc. 29), at 9: "This Court should hold that res judicata bars any further challenges to Missouri's method of lethal injection."

Similarly unpersuasive are Defendants' arguments about the motions to intervene filed by Bucklew, Ringo and Middleton. Those filings suggest, at most, that these plaintiffs wished to engage in joint discovery and other litigation because they, like the *Clemons* plaintiffs, were death-sentenced inmates against whom the Attorney General's Office had sought execution dates.[41] That similarity does not create "privity" under *Taylor v. Sturgell* or undermine the longstanding presumption that judgments do not bind non-parties, in light of our "deep-rooted historic tradition that everyone should have his own day in court."[42]

2. Different defendants

Defendants also fail to prove that the two cases involve the same anonymous defendants. As explained above, it is unknown whether today's execution team has the same membership as the one sued in *Clemons*. It is unknown whether the people who procure, dispense and administer the lethal injection drugs are the same as in *Clemons*. And it is unknown whether any of the John Doe parties may have gained or lost the necessary credentials to obtain and handle the drugs at issue.

It may be, for example, that previous Missouri executioners had the requisite credentials and complied with the FDCA and CSA, while the current members do not. The defendants in *Clemons* insist that the DOC does not any longer use the services of "Dr. John Doe No.1"[43]—a dyslexic surgeon who had trouble reading the dosages he was administering, and who varied the amount of thiopental he injected from execution to execution. We do not know Dr. Doe's

---

[41] *See id.* at 7-8 (citing "common stake in a positive outcome," shared legal interests, and plans to pursue joint discovery and rest on civil complaint filed by pre-existing plaintiffs).

[42] 128 S. Ct. at 2171.

[43] *See* Appellees' Brief in *Clemons et al. v. Crawford et al.*, Eighth Circuit Case No. 08-2895, at 35; Brief of Appellant Clemons, at 35.

qualifications to prescribe Class III controlled substances, or whether he complied with federal law when administering the thiopental. The *Clemons* defendants likewise insist that they have brought an anesthesiologist to the team.[44] But we do not know this practitioner's credentials, his or her compliance with the federal statutes at issue in this suit, or the degree of his or her hands-on involvement with executions. Nor do we know the extent to which the anesthesiologist is supervising another member of Missouri's team: a nurse with a conviction for aggravated stalking.[45] If *that* individual is the one obtaining or dispensing the drugs, his criminal history may make those activities unlawful.[46]

3. Substantially different operative facts.

Res judicata bars claims that were actually litigated in a previous suit, as well as claims that could have been asserted from the "same nucleus of operative facts."[47] Preclusion depends on whether "the wrong sought to be addressed is the same in both actions."[48] A party who brings a suit to judgment, then, may not bring a second suit involving the same facts but a different legal

---

[44]*Clemons*, Appellee's Br. at 55.

[45]*Id.* at 32; Brief of Appellant Clemons, at 49; *see also* Jeremy Kohler, "Execution Nurse Had Criminal Past," *St. Louis Post-Dispatch*, Jan. 20, 2008, available at 2008 WLNR 1126302.

[46]An "advance practice registered nurse" in Missouri may dispense or prescribe Schedule III controlled substances as part of a "collaborative practice agreement" with a physician who is federally licensed to do so. Mo. Rev. Stat. § 195.070.2. The federal government, in turn, may revoke a physician's license to dispense or prescribe controlled substances if the physician's actions are such that his or her license is "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). That determination includes "conduct which may threaten the public health and safety." 21 U.S.C. § 823(f)(5). Such conduct may presumably include professional collaborations with violent individuals. *See* Kohler, *supra*, 2008 WLNR 1126302 (quoting a supervisor within the Missouri Division of Probation and Parole as stating, "[I]t seems bizarre to me that we would knowingly allow an offender, on active supervision, to participate in the execution process at any level.").

[47]*In re Ladd*, 450 F.3d 751, 753 (8th Cir. 2006); *Costner v. URS Consultants*, 153 F.3d 667, 673 (8th Cir. 1998).

[48]*Hicks v. O'Meara*, 31 F.3d 744, 746 (8th Cir. 1996).

theory.[49] But mere factual overlap between two suits does not mean they involve the same "cause of action."[50] This suit involves different operative facts from *Clemons* and also involves ongoing violations. Thus, the final requirement for res judicata does not apply.

a. *Different wrongs*

The two lawsuits concern substantially different facts creating different wrongs. Defendants correctly observe that *Clemons* involved "whether the Missouri Department of Corrections had failed to properly train the persons who carry out executions by lethal injection."[51] The issue there was, and remains, whether the execution team's ill-trained or otherwise incompetent personnel will reliably implement the DOC's protocol as it is written, rather than subject an executed prisoner to a risk of excruciating pain if he is not adequately anaesthetized by thiopental before the administration of pancuronium bromide and potassium chloride. The DOC's inadequate vetting of personnel includes its previous use of a dyslexic physician who could not read the dosages he administered, and gave varying amounts of three drugs from execution to execution. It was also revealed that a current member of the execution team is a nurse practitioner with a conviction for aggravated stalking.

The issues in this case are "arguably related," but different.[52] They have nothing to do with whether Defendants are or will become capable of following the written protocol. In fact,

---

[49]*Lane v. Peterson*, 899 F.2d 737, 744 (8th Cir. 1990).

[50]*See*, *e.g.*, *Hicks*, 31 F.3d at 746; *Ladd*, 450 F.3d at 754; *NLRB v. United Technologies Corp.*, 706 F.2d 1254, 1259-60 (2nd Cir. 1983) ("[T]he circumstance that several operative facts may be common to successive actions between the same parties does not mean that the claim asserted in the second is the same claim that was litigated in the first.").

[51]Amended Motion to Dismiss (ECF Doc. 29), at 6.

[52]*See Hicks*, 31 F.3d at 746. In *Hicks*, a wrongful termination case did not preclude a later suit for non-payment of wages under the Fair Labor Standards Act, even though both cases involved the firing of an employee without adequate and agreed-to compensation.

Defendants could follow the written protocol word for word and still run afoul of the FDCA and the CSA. Further, with the exception of whether the person administering the drugs is permitted to do so under the FDCA and CSA, this suit has nothing to do with the actual carrying out of the execution—the sole focus of *Clemons*—but instead deals with a preliminary, but much earlier step: how the drugs are obtained.

Thiopental, for example, is a schedule III controlled substance. The CSA requires, among other things, that thiopental be prescribed by a doctor medically licensed to prescribe it.[53] The core fact of the claim is that Defendants have not legally obtained the drugs they plan to inject—whether or not they will inject them competently, and whether the DOC intends to use a dyslexic surgeon, an aggravated stalker, or someone else. Likewise, the FDCA limits who can dispense and obtain controlled substances and prohibits using a drug for a purpose not authorized by the FDA. The FDA has not approved thiopental, pancuronium bromide, and/or potassium chloride for lethal injections. This allegation, too, is outside the scope of *Clemons*. It has nothing to do with the State's failure to hire or train competent execution personnel—the issue in *Clemons*—but instead deals with whether Defendants are authorized and licensed to administer the drugs they intend to use.

Defendants insist that both cases concern the discrete act of executing a prisoner with lethal chemicals. But that does not make the causes of action identical. "This approach is too simplistic and fails to consider all of the underlying facts necessary to prove each separate claim."[54] Although both suits involve lethal injection, "they are independent of each other and

---

[53]21 U.S.C. § 829(b).

[54]*Hicks*, 31 F.3d at 746.

seek to redress different injuries resulting from distinct conduct."[55] In a related context, the Ninth Circuit held that a prisoner's "generic" Eighth Amendment claim against lethal injection on habeas review did not preclude the prisoner's later and more focused attack on California's lethal injection protocol under section 1983.[56]

Defendants' own motion shows that the two cases involve substantially different issues. The motion argues, among other things, that the State's use of thiopental does not violate the CSA or the FDCA because Defendants are not using the drug for therapeutic purposes, but rather, to bring about death.[57] But *Clemons* involved quite a different purpose of thiopental—or so the defense told Judge Gaitan and maintains on appeal. *Clemons* held that the DOC's use of thiopental adequately ensures that the prisoner will be unconscious before the other drugs are administered, and thus, that there is no significant risk of suffering.[58] The same argument prevailed before the Eighth Circuit in *Taylor v. Crawford*.[59] These holdings recognize a medical purpose behind thiopental: to prevent the prisoner from suffering pain from the other two drugs. The State's sudden disavowal of that purpose is yet a further indication that this suit and *Clemons* involve substantially different circumstances.

---

[55]*Costner*, 153 F.3d at 674.

[56]*Beardslee v. Woodford*, 395 F.3d 1064, 1068-69 (9th Cir. 2005).

[57]*See* Amended Motion to Dismiss (ECF Doc. 29), at 17 ("The sole purpose of the thiopental is to execute the inmate in a strictly controlled and regulated procedure."); *id.* at 18 ("Missouri uses thiopental in executions specifically because thiopental causes death at high doses.").

[58]*See Clemons*, ECF Doc. 89 (order granting judgment on the pleadings), at 3 ("After the five grams of thiopental are injected, the medical personnel physically examine the prisoner to confirm unconsciousness. After confirming unconsciousness, the second and third chemicals are injected, if at least three minutes have passed since the thiopental was injected.").

[59]487 F.3d 1072, 1083-84 (8th Cir. 2007). If Defendants were correct in invoking res judicata, then one must wonder why *Clemons* itself is not claim-precluded by *Taylor*—or, indeed, why the Eighth Circuit is troubling itself with the merits of the plaintiffs' Eighth Amendment claims.

b. *Ongoing violations*

Res judicata is particularly problematic in cases of multiple and ongoing acts of misconduct.[60] Judge Sachs recognized as much in *CLEAN v. Premium Standard Farms*.[61] There, a large-scale hog operation built separate facilities without the required discharge permits from the EPA. Each construction separately violated the Clean Water Act. Citizen suits on those violations, in turn, were not barred by previous litigation between the State of Missouri and the defendant. Even if the citizens were considered to be "privies" of the State, the two suits did not involve permit violations from the same hog facilities. The defendant "built each source separately, engaged in separate (albeit related) acts to operate them, and separately failed to obtain a permit for each of them."[62]

The same is true of Defendants in this case, who plan to violate federal law with each batch of lethal drugs that they illegally obtain, dispense, and administer. Without discovery, we do not even know whether these actions are the same from execution to execution—for example, where the DOC obtains the drugs, or the credentials of the person who requisitions them. Such future nuclei of yet-occurring facts were necessarily beyond the scope of *Clemons*. That does not mean that a new lawsuit may freely proceed with each and every future execution, as Defendants worry.[63] It does mean that future claims will be barred only by *stare decisis* if they involve issues resolved on materially indistinguishable facts, but they will not be precluded by *res judicata* simply because they involve lethal injection in Missouri.

---

[60]*Lawlor v. National Screen Service Corp.*, 349 U.S. 322, 327-28 (1955).

[61]No. 97-6073-CV-SJ-6, 2000 WL 220464, at *5-*7 (W.D. Mo. Feb. 23, 2000).

[62]*Id.* at *5.

[63]Amended Motion to Dismiss (ECF Doc. 29), at 9.

III. Plaintiffs may invoke the FDCA and the CSA in seeking declaratory relief.

Defendants argue that Plaintiffs lack a "private right of action" to proceed under the FDCA or the CSA. As to the FDCA, Defendants invoke 21 U.S.C. § 337(a), which requires that suits to "enforce" or to "restrain violations" of the statute must be brought by the United States.[64] As to the CSA, Defendants argue that no provision of federal law confers a private right to invoke such a "garden-variety criminal statute."[65] These arguments fail because the present suit does not seek to "enforce" the statutes or "restrain" violations of them. First, the courts have routinely permitted declaratory judgment actions by non-government parties under the FDCA and even the CSA, so that parties will know whether a proposed course of conduct will violate the statute. Second, the FDCA, in particular, specifies a narrow class of private declaratory actions that are forbidden at specific times, thus suggesting that other declaratory actions are permitted.

A. An affected private party may seek a declaration of whether a course of conduct violates the FDCA or CSA, as shown by the prohibition limited to private suits that "enforce" the FDCA, as well as the fact that private parties have been permitted to bring declaratory judgment actions under these statutes.

Defendants overstate the prohibition on private suits to "enforce" the FDCA. The statute provides that the federal government must bring any proceeding "for the enforcement, or to restrain violations, of this chapter."[66] But it does not purport to limit declaratory judgment actions. As a general matter, the express inclusion of one thing in a statute implies the exclusion of others not mentioned.[67] If Congress wished to preclude declaratory relief, it would have.

---

[64] *Id.* at 10.

[65] *Id.* at 11.

[66] 21 U.S.C. § 337(a).

[67] *See*, *e.g.*, *United States v. Stuckey*, 220 F.3d 976, 985 (8th Cir. 2000).

More specifically, the courts have roundly permitted private parties to bring declaratory actions under the FDCA so that parties can know whether their conduct will violate the statute. In *Medical Center Pharmacy v. Mukasey*, for example, a group of pharmacies sought a declaration that the FDCA did not apply to "compounded" drugs.[68] The Fifth Circuit at least partly agreed, holding that compounded drugs were "new drugs" requiring FDA approval but might fall under certain exceptions to that requirement.[69] Similarly, in *American Health Products Co. v. Hayes*,[70] and *Nutrilab v. Schweiker*,[71] the manufacturers of certain bean-based "starchblockers" were allowed to seek a declaration of whether the product was a "food" or a "drug" under the FDCA. The courts in both cases held that starchblockers were a "new drug" requiring FDA approval as safe and effective, and allowing regulation and seizure by the agency.[72]

A manufacturer may likewise seek a declaration that its product is not a "new drug" subject to FDA approval, but rather, a "generic" or "me too" drug that is bioequivalent to a drug already approved, which allows the manufacturer to present a less onerous "abbreviated new drug application."[73] In *Premo Pharmaceutical Laboratories v. United States*, the Second Circuit specifically held that the district court had jurisdiction to entertain the declaratory judgment

---

[68] 536 F.3d 383, 387, 392 (5th Cir. 2008).

[69] *Id.* at 406.

[70] 574 F. Supp. 1498 (S.D.N.Y. 1983), *aff'd*, 744 F.2d 912 (2nd Cir. 1984).

[71] 713 F.2d 335 (7th Cir. 1983).

[72] *American Health Products*, 574 F. Supp. at 1509-10; *Nutrilab*, 713 F.2d at 338-39.

[73] *Premo Pharmaceutical Labs. v. United States*, 629 F.2d 795, 798-99 (2nd Cir. 1980), and authorities cited.

action.[74] The Government had already instituted numerous proceedings to seize the drugs in question. A declaratory judgment—as opposed to an injunction—was permissible, because it left the Government free to seize the drugs while the suit remained pending.[75]

The present case is analogous to *Medical Center Pharmacy*, the "starchblocker" cases, and *Premo*. None is an action to "enforce" the FDCA, and none is brought by the federal government, but all seek a declaration of the FDCA's scope so that concerned parties may conduct their affairs accordingly. It is true that the plaintiffs in the other cases were purveyors of drugs, while the present Plaintiffs stand to be involuntarily injected with them. But that distinction makes the present Plaintiffs even *more* entitled to seek a declaratory judgment. The FDCA exists to ensure that drugs are not only "safe" but also "effective" for their "intended use."[76] The intended use of thiopental is to make the prisoner unconscious so that he suffers no pain from the administration of pancuronium bromide or potassium chloride.[77] Considerably more than drug manufacturers, Plaintiffs fall within the class of persons being protected by the FDCA—a statute that should be read broadly to achieve its remedial purposes.[78]

---

[74] *Id.* at 801.

[75] *Id*; *see also County of Santa Cruz v. Gonzales*, No. C 03-01802 JF, 2008 WL 3892019 (N.D. Cal. Aug. 20, 2008) (declining to dismiss claim for declaratory and injunctive relief that federal enforcement of the CSA against "medical marijuana" facilities violated the Tenth Amendment).

[76] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).; 21 U.S.C. § 393(b)(2)(B).

[77] *Baze v. Rees*, 128 S. Ct. 1520, 1533-34 (2008); *Taylor v. Crawford*, 487 F.3d 1072, 1083-84 (8th Cir. 2007).

[78] *American Health Products*, 574 F. Supp. at 1503.

B. The FDCA's express prohibition of certain private declaratory judgment actions shows that the statute allows *other* such private actions for a determination of whether the statute has been complied with.

Aside from generally permitting declaratory judgment suits by private parties, the FDCA goes so far as to expressly prohibit certain types of declaratory actions at certain times. These provisions concern patent infringement suits during a manufacturer's application to market a "generic" drug. When a manufacturer first seeks FDA approval for a new drug, it must list any patents that cover the drug.[79] The FDA publishes this list of patents for each approved drug in its so-called "Orange Book."[80] When a later manufacturer seeks to market a "generic" version of the drug, the applicant must certify that the proposed generic does not infringe any valid patent that was listed.[81] The applicant must provide notice of this certification to the holder of the original "new drug" approval.[82] "Original" and "generic" marketers are frequently engaged in patent disputes during the application process. To facilitate that process, the FDCA expressly prohibits the original licensee from filing a declaratory judgment action on whether its patent has been infringed, until 45 days have passed since the notice of the generic application.[83]

The FDCA prohibition has been construed to reach only those declaratory actions that address whether a patent has been infringed or is invalid.[84] The statute therefore permits other types of declaratory judgment actions. In *Ben Venue Laboratories v. Novartis Pharmaceutical*

---

[79]21 U.S.C. § 355(j)(7)(A)(iii).

[80]*Ben Venue Laboratories v. Novartis Pharmaceutical Corp.*, 10 F. Supp. 2d 446, 448-49 (D.N.J. 1998), describing statutory framework.

[81]21 U.S.C. § 355(j)(2)(A)(vii).

[82]21 U.S.C. § 355(j)(2)(B)(ii).

[83]21 U.S.C. §§ 355(c)(3)(D)(i)I), (j)(5)(C)(i)(I).

[84]*Ben Venue*, 10 F. Supp. 2d at 451-42.

Corp., for example, a company sought FDA approval for a "generic" version of the drug Aredia, which treats bone loss. The "generic" company also brought a declaratory judgment action in the district court. That action sought a declaration that the "original" company's patent did not actually cover Aredia, and thus, should not have been listed in the FDA's "Orange Book." The court held that it had jurisdiction to consider the suit on its merits.[85] The plaintiff, after all, sought a declaration that the defendant's patent did not cover the "original" drug in question, and should not have been listed as such by the FDA. It did not seek a declaration that the patent was invalid or that the proposed "generic" would not infringe it. The court ultimately concluded that the patent was properly listed in the "Orange Book," or at least that the plaintiff was unlikely to succeed on its claim to the contrary.[86]

The present declaratory judgment action is permissible under the reasoning of *Ben Venue*. The FDCA expressly prohibits specific types of declaratory judgment actions, but not others. It permits a declaratory action addressing whether a party has complied with the Act. In *Ben Venue*, the question was whether the defendant manufacturer violated the FDCA by listing a patent that did not apply to its approved drug, and in this case, the question is whether Defendants have violated the FDCA by their plans to obtain, dispense, and administer drugs without the FDA's approval that the drugs are safe and effective for their intended use.

IV. The language and purpose of the FDCA and the CSA apply to lethal injections.

Defendants argue that the FDCA and the CSA do not preempt state law concerning lethal injection and that the FDCA and the CSA generally do not apply to lethal injection. Specifically, Defendants argue that the FDCA and CSA do not preempt state law regarding lethal injection

---

[85] *Id.* at 450-52.

[86] *Id.* at 453-58.

because: 1) Congress did not intend to bar states from regulating controlled substances under the CSA or the FDCA and Congress has not barred states from carrying out lethal injections with the drugs used by Missouri and the federal government; 2) no federal agency has ruled that a state cannot use the drugs Missouri uses for lethal injections; and, 3) the purposes of the FDCA and the CSA do not involve lethal injections. These arguments fail because Defendants' actions may violate federal law whether or not state law is preempted by federal law, and also because Defendants ignore the plain language of the federal statutes while favoring some of the statutes' purposes over others, including the purpose of ensuring that drugs are effective for their intended use—such as thiopental's purpose of preventing suffering during an execution.

A. Plaintiffs need not show that the FDCA or CSA comprehensively preempt state law in order for Defendants' actions to violate federal law.

All of Defendants' substantive arguments rest on the premise that the FDCA and CSA do not preempt Missouri law. That premise is a red herring. A state actor may violate federal law whether or not the federal law "preempts" any state law. In a case brought under 42 U.S.C. § 1983, for example, we might examine whether an arrest without probable cause violated the Fourth Amendment. The plaintiff would not have to separately show that the Fourth Amendment or section 1983 "preempts" whatever state law may govern searches and seizures. Likewise, in this case, there is no relevant Missouri statute or regulation to be "preempted." Missouri's method-of-execution statute provides that prisoners must be put to death by "the administration of lethal injection" or "the administration of lethal gas."[87] Nothing in the statute requires the DOC to use thiopental, some other controlled substance, or any substance that violates federal law. Likewise, there is no state regulation to be "preempted" by federal statute. The DOC

[87]Mo. Rev. Stat. § 546.720.1.

unilaterally chooses which chemicals to use and how to obtain and administer them. Those decisions lie outside the Missouri Administrative Procedure Act.[88]

The lack of a preemption issue distinguishes this case from the Delaware trial court's ruling in *State v. Deputy*.[89] The issue in *Deputy* was whether the FDCA and CSA preempted a statute expressly providing that lethal injection is not a "medical" procedure, and expressly authorizing "any pharmacist or pharmaceutical supplier" to dispense the chemicals without a prescription.[90] Mr. Deputy therefore argued that Delaware's statute was preempted, since his claim was that federal law required a prescription for the drugs. Plaintiffs in this case, by contrast, challenge only the individual actions of Defendants in seeking to carry out their executions. The dispositive question is whether Defendants' actions violate federal law, not whether federal law systematically preempts Missouri law.

B. The plain language of the FDCA and CSA applies to lethal injections that involve substances which are regulated by those statutes, and therefore, the fact that Congress has not prohibited Missouri from enacting and enforcing state law regulating controlled substances is irrelevant to whether Defendants are violating or will violate the FDCA and CSA.

Defendants argue that the FDCA and CSA cannot apply to lethal injections because Congress did not intend to prohibit the states from regulating controlled substances, as evidenced by the fact that every state has a controlled substances law, and because the federal government uses the same drugs in lethal injection as Missouri does.

But the fact that states have controlled substances laws is irrelevant to whether Defendants have violated or will violate the FDCA and CSA. Similarly, the fact that Congress

---

[88] *Middleton v. Missouri Dept. of Corrections*, 278 S.W.3d 193, 195-98 (Mo. 2009).

[89] 644 A.2d 411, 417-19 (Del. Super. 1994).

[90] *Id.* at 417 (citing 11 Delaware Code § 4209(f)).

has not prohibited the use of particular drugs in lethal injections or that the federal government uses the same drugs as Missouri sheds no light on the issue. The statute governing executions by the federal government—18 U.S.C. §3596—does not mention the drugs used in lethal injections. If the CSA or FDCA could apply to lethal injections, there would be no reason to pass an additional statute specifically outlawing particular drugs for lethal injections. The fact that no such statute exists may suggest either that Congress thought the FDCA and CSA already covered the issue, or, at most, that Congress has not considered the question, in which case the statutes' plain language should govern.

The statutory language itself supports Plaintiffs' position. The CSA provides that "no controlled substance in schedule III or IV . . . may be dispensed without a written or oral prescription."[91] Thiopental is a Schedule III controlled substance.[92] And Defendants have had, or will have, some source from which the thiopental is "dispensed" so that they can inject it into Plaintiffs. The statute's plain language requires not only a prescription, but a prescription issued through a practitioner who is federally licensed and registered to issue it.[93] To dispense a controlled substance in violation of the CSA is "unlawful."[94] The FDCA is to similar effect. Its definition of "drugs" includes "articles intended for use in the diagnosis, cure, ***mitigation***, treatment, or prevention of disease in man or other animals" and "articles . . . ***intended to affect the structure or any function of the body*** of man or other animals."[95] Any "drug" that is unsafe

---

[91]21 U.S.C. § 829(b).

[92]*See* <<http://www.deadiversion.usdoj.gov/schedules/listby_sched/sched3.htm>>.

[93]21 U.S.C. § 822(a).

[94]21 U.S.C. § 842(a)(1).

[95]21 U.S.C. § 321(g)(1)(B), (C) (emphases added).

for use except under a licensed practitioner's supervision may be dispensed only upon a prescription from "a practitioner licensed by law to administer such drug."[96] More generally, a person may not introduce a "new drug" into interstate commerce without FDA approval, which requires, among other things, a detailed showing that the drug is effective for its intended use.[97] No such approval has been given for the use of thiopental, pancuronium bromide, or potassium chloride for executions—including the use of thiopental to ease or prevent pain. Yet, all of these substances are "drugs"; Defendants will use them to "affect the function of the body" by terminating that function altogether.

More tellingly, the statutes permit exemptions for particular types and usages of drugs by particular types of people. The CSA, for example, requires that a person who dispenses a controlled substance must be registered to do so by the Attorney General.[98] Exceptions to this requirement have been promulgated by regulation and include, among others:

- Employees or agents of registered persons,[99]
- Practitioners who are agents or employees of hospitals registered to dispense controlled substances,[100]
- Federal, state, or local officers who, when enforcing laws and regulations governing controlled substances, may possess such substances in the course of their duties,[101] and

---

[96] 21 U.S.C. § 353(b)(1).

[97] 21 U.S.C. § 355(a),(b).

[98] 21 U.S.C. § 822(a).

[99] 21 C.F.R. § 1301.22(a), (b).

[100] 21 C.F.R. § 1301.22(c).

[101] 21 C.F.R. § 1301.24(a)(1), (a)(2).

●Practitioners who dispense Schedule III, IV or V controlled substances for detoxification treatment, under certain conditions.[102]

The CSA contains no such exemption for lethal injection.[103] The issue of applying the FDCA and CSA to executions has been a matter of public interest at least since the Supreme Court's 1985 ruling in *Heckler v. Chaney*.[104] And lethal injection has been a prominent issue in death penalty litigation for several years. *Expressio uni us est exclusio alterius:*[105] if Congress wished to exempt executions from otherwise applicable law, it would have done so, just as the State of Utah has.[106] This Court cannot read into a statute an exception that is not there.

C. Whether a federal agency has expressly ruled that particular drugs cannot be used in lethal injections has nothing to do with whether the FDCA and the CSA apply to lethal injection.

Because the FDA has not enforced the FDCA or the CSA in the context of lethal injections, Defendants argue that how Missouri obtains and administers lethal injection drugs does not violate the FDCA or the CSA. This argument, too, is unavailing. First, whether a government agency enforces a statute has nothing to do with whether the statute has been

---

[102]21 C.F.R. § 1301.28(a)(1-3).

[103]Similarly, the FDCA permits the FDA, by regulation, to exempt any "drug" from the statutory approval requirements whenever "such requirements are not necessary for the protection of the public health." 21 U.S.C. § 353(b)(3). But the agency has not promulgated any such regulation for lethal injection chemicals.

[104]470 U.S. 821 (1985).

[105]*United States v. Stuckey*, 220 F.3d 976, 985 (8th Cir. 2000).

[106]Utah Reg. R. 156-37-301(q). The regulation requires the issuance of state controlled substance licenses to "the Utah Department of Corrections for the conduct of execution by the administration of lethal injection under its [Utah] statutory authority and in accordance with its policies and procedures."

violated. An action either violates a law or it does not. That does not and has never turned on whether enforcement is sought.

Second, Defendants' reliance on *Heckler v. Chaney* and the FDA's statement from that litigation is misplaced.[107] *Heckler* held that a prisoner could not compel governmental enforcement of the FDA against those who carry out lethal injections. But we know from the district court's ruling in *Roane v. Holder* that prisoners may challenge the FDA's *general* policy of non-enforcement against federal executioners, as opposed to its decision not to enforce the FDCA in a particular case.[108] It is exceedingly doubtful that the *Roane* court would allow such a suit to proceed if the FDCA were simply inapplicable to lethal injections as a matter of law.

For that matter, the FDA's decades-old statement concerning enforcement of these statutes does not account for significant advances in scientific knowledge about lethal injections, including the universally acknowledged fact that a prisoner will suffer excruciating pain if he is not adequately anesthetized before being injected with potassium chloride.[109] When the FDA decided not to enforce its regulation in the context of lethal injections, resulting in the *Heckler* litigation, not a single execution by lethal injection had taken place. Only eight lethal injections had been carried out when the Supreme Court decided *Heckler* in 1985, compared to 994 since that time.[110] And, of course, even if the FDA had been aware of today's circumstances at the

---

[107]Amended Motion to Dismiss (ECF Doc. 29), at 16; *Heckler v. Chaney*, 470 U.S. 821, 824-25 (1985).

[108]*Roane v. Holder*, 607 F. Supp. 2d 216, 227 (D.D.C. 2009).

[109]*Baze v. Rees*, 128 S. Ct. 1520, 1533 (2008) ("It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride.").

[110]Information available at <<http://www.deathpenaltyinfo.org/executions>>.

time of its statement, a decision not to enforce the statutes would not mean that Defendants' actions are automatically "legal."

D. Plaintiffs' claims are supported by the FDCA's and CSA's purpose of ensuring that therapeutic drugs are effective for their intended use, including the use of thiopental to prevent an execution from causing severe pain.

Defendants argue that the FDCA and CSA cannot apply to lethal injection because the purposes of those statutes are inapposite to the purpose of lethal injection. Setting aside the fact that the Court must follow what Congress says rather than what Congress may "mean"—see Section B, above—the use of thiopental in lethal injections still falls within the purpose of the applicable federal statutes.

A central purpose of the FDCA is to ensure that a "drug" is "safe and effective for its intended use."[111] The CSA likewise envisions that the prescriptions required for controlled substances will be issued for "a legitimate medical purpose."[112] For example, a drug that is intended to relieve pain must be known to actually do so before it can be administered for that purpose. The FDCA, through the FDA's approval of drugs for particular uses, attempts to ensure that. That is why studies are conducted on drugs before they can be marketed and administered.[113] Thiopental is administered in lethal injections to ensure that death-sentenced inmates do not suffer excruciating pain during execution.[114] Thus, the purpose for which it is administered is therapeutic, and the FDCA helps to ensure that any therapeutic drug is "effective

---

[111] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *United States v. Lane Labs-USA*, 324 F. Supp. 2d 547, 563-64 (D.N.J. 2004); 21 U.S.C. § 393(b)(2).

[112] *See* 21 C.F.R. § 1306.04(a).

[113] *See* 21 U.S.C. § 355(b).

[114] *See Clemons*, ECF Doc. 89, at 3; *Taylor v. Crawford*, 487 F.3d 1072, 1083-84 (8th Cir. 2007).

for its intended use." Plaintiffs' suit therefore strikes at "***the*** core objective of the FDCA."[115] The therapeutic aspect of lethal injections is underscored by recent events in Ohio, where executioners spent two hours trying, without success, to "humanely" execute Romell Broom.[116]

Seeking to avoid the statutes' purposes, Defendants insist that they use thiopental in executions "specifically because thiopental causes death at high doses," and not to reduce the risk of suffering.[117] But that is directly contrary to what the DOC and its agents told the district court in *Clemons* and the Eighth Circuit in *Taylor v. Crawford*—only for both courts to rule that the DOC's use of thiopental so minimizes the risk of suffering that the prisoners could not show an Eighth Amendment violation. [118] In *Clemons*, for example, the DOC insisted that its "stringent" safeguards exceeded those in place in Kentucky, whose protocol the Supreme Court had upheld:

> Not only is a more than ample amount of thiopental administered to cause loss of unconsciousness (sic) . . . but, in between the administration of the thiopental and the next two chemicals, a medical professional enters the execution chamber to both check the IV site for any misadministration of the thiopental and to make a direct assessment of consciousness.[119]

In *Taylor*, the DOC similarly argued, at length, that "The first chemical, thiopental, renders the condemned unconscious ***so that the execution is humane***."[120]

---

[115]*Lane Labs*, 324 F. Supp. 2d at 563 (emphasis added).

[116]Peter Krouse, "Strickland Stops Execution After Team Can't Access Veins,"*Cleveland Plain Dealer*, Sept. 16, 2009.

[117]Amended Motion to Dismiss (ECF Doc. 29), at 18.

[118]*See Clemons*, ECF Doc. 89, at 3; *Taylor v. Crawford*, 487 F.3d 1072, 1083-84 (8th Cir. 2007).

[119]*Clemons*, ECF Doc. 47 (motion for judgment on the pleadings), at 10.

[120]Appellant's Brief in *Taylor*, Eighth Circuit Case No. 06-3651, at 40 (available at 2006 WL 3857886).

Defendants' opportunistic about-face should raise judicial eyebrows. The equitable doctrine of judicial estoppel gives the Court discretion to "protect the integrity of the judicial process by preventing a litigant from playing fast and loose with the courts."[121] In *New Hampshire v. Maine*, the Supreme Court explained that, "[w]here a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him."[122] Defendants, then, should be estopped from denying the medicinal purpose of thiopental—the very basis on which Missouri's execution protocol has been upheld. Their current argument calls into question the correctness of *Taylor* and *Clemons*, for the stark contradiction "create[s] the perception that either the first or the second court was misled."[123] It also suggests that Missouri's lethal injection procedures may violate the rule of *Baze* because, if the sole purpose of thiopental is to cause death, then 1) there is no legitimate reason to administer two additional drugs that will cause severe pain, and 2) there is no drug being administered for the purpose of alleviating the risk that pancuronium bromide and potassium chloride will cause severe pain.[124]

In any event, and even without estoppel, Defendants cannot prove from the pleadings alone that their drugs serve no medicinal purpose. The motion to dismiss must be denied.

---

[121] *New Hampshire v. Maine*, 532 U.S. 742, 750 (2001); *Russell v. Rolfs*, 893 F.2d 1033, 1037 (9th Cir. 1990).

[122] *New Hampshire*, 532 U.S. at 749.

[123] *Id.* at 750.

[124] *See Baze v. Rees*, 128 S. Ct. 1520, 1533 (2008) ("It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride.").

Conclusion

The Court should deny the amended motion because the grounds asserted do not justify dismissal. Plaintiffs have standing because the declaration they seek is likely to induce statutory compliance by law-abiding public officials. They are not barred by any res judicata effect of the *Clemons* litigation, which involves different prisoners and different violations of law arising from different facts at different times. They may invoke the FDCA and CSA in seeking a declaratory judgment, as other courts have allowed other private parties to do. And they have viable claims under the plain language and core purpose of both statutes.

Respectfully submitted,

/s/ Joseph W. Luby
Joseph W. Luby, Mo. Bar 48951
Public Interest Litigation Clinic
6155 Oak Street, Suite C
Kansas City, MO 64113
816-363-2795 • FAX 816-363-2799
Counsel for Plaintiff Winfield

David Barron, Ky. Bar 90269
100 Fair Oaks Lane, Suite 301
Frankfort, KY 40601
502-564-3948 • FAX -502-564-3949
Counsel for all Plaintiffs

John William Simon, Mo. Bar 34535
Constitutional Advocacy, L.L.C.
2683 South Big Bend Blvd. #12
St. Louis, MO 63143-2100
314-604-6982 • FAX 314-765-2605
Counsel for Plaintiffs Bucklew and Middleton

Cheryl Ann Pilate, Mo. Bar 42266
Rebecca L. Kurz, Mo. Bar 40451
Morgan Pilate LLC
142 North Cherry
Olathe, KS 66061
913-829-6336 • FAX 913-829-6446
Counsel for Plaintiffs Bucklew, Middleton, and Ringo

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was forwarded for transmission via Electronic Case Filing (ECF) this 16th day of September, 2009, to Andrew W. Hassell, Michael J. Spillane and Stephen D. Hawke, Office of the Attorney General, P.O. Box 899, Jefferson City, Missouri 65101.

/s/ Joseph W. Luby
Joseph W. Luby

Counsel for Plaintiff John E. Winfield